

## **II. REMARKS**

### **A. Introduction**

Applicants submit this Amendment in a bona fide attempt to (i) advance the prosecution of this case, (ii) answer each and every ground of objection and rejection as set forth by the Examiner, (iii) place the claims in a condition for allowance, and (iv) place the case in better condition for consideration on appeal. Applicants respectfully request reexamination and reconsideration of the above referenced patent application in view of this Amendment.

Claims 1-4, 6, 8-11, 15-17 and 21-22 are currently pending in the application. As indicated above, Claims 1, 6 and 10 have been amended. Claims 2-4, 8-9, 11, 15-17 and 21-22 have also been canceled.

Applicants respectfully submit that the noted amendments merely make explicit that which was (and is) disclosed or implicit in the original disclosure. The amendments thus add nothing that would not be reasonably apparent to a person of ordinary skill in the art to which the invention pertains.

### **B. Claim Objections**

The Examiner has objected to Claims 2, 6, 16 and 17 for various informalities. As indicated above, Claims 2, 16 and 17 have been canceled.

In Claim 6 the phrase “waveforms that are representative of waveforms naturally generated within a body...” has been amended to read “waveforms that are generated in a body...”.

### **C. Response to Rejections**

#### **1. 35 U.S.C. § 112**

The Examiner has rejected Claims 1-4, 16-19, 21 and 22 under 35 U.S.C. § 112, first paragraph, “as failing to comply with the written description requirement.” The Examiner contends:

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification, as originally filed, provides support for transmitting a waveform selected from a plurality of collected waveforms to the body in order to regulate a body organ, but fails to disclose that the first waveform signal transmitted to the body to control organ function includes at least a second waveform that

substantially corresponds to at least one of the collected waveforms and is operative in the regulation of the body organ.

The Examiner has also rejected Claims 1-4, 6, 8-19, 21 and 22 under 35 U.S.C. § 112, second paragraph, “as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.” The Examiner contends, *inter alia*:

Regarding claims 1, 21 and 22, the step of transmitting recited in each claim requires that the first waveform signal includes a second waveform. There does not appear to be a first waveform recited prior to the recitation of the second waveform. Furthermore, it is unclear from the claim language whether the first waveform signal is the same waveform as the second waveform, such that the recitation of a second waveform potentially fails to further limit the first waveform signal. It is indefinite whether the transmitting step is attempting to claim that a plurality of collected waveforms are being transmitted to the body or if a single waveform is being transmitted to the body where differing terminology is used to define the single waveform signal.

Claim 4 recites the limitations “the function” and “said connected waveforms” in line 3. There is insufficient antecedent basis for these limitations in the claim. There are no waveform functions or connected waveforms recited in the claims prior to these recitations.

Regarding claim 6, it is unclear how waveforms that are *indicative* of body organ functioning can be operative to stimulate or regulate a first body organ.

Claim 11 recites the limitation “said collecting means” in line 2. There is insufficient antecedent basis for this limitation in the claim. There are no collecting means recited in the claims prior to this recitation.

As indicated above, Claims 2-4, 8-9, 11, 15-17 and 21-22 have been canceled. Claims 1 and 6 have been amended to reflect the transmission of at least one waveform from a collected plurality of waveforms to a body organ. As noted by the Examiner, the noted amendment is in accord with and, hence, supported by the Specification.

The term “indicative” has also been deleted in Claim 6 and replaced with the phrase “operative in the regulation”.

Claim 10 has also been amended to reflect “collecting means” to provide the requisite antecedent basis for the term in Claim 11.

Applicants submit that Claims 1, 6 and 10 are now in accord with the mandates of 35 U.S.C. § 112. Applicants accordingly respectfully request that the objections under 35 U.S.C. § 112 be withdrawn.

## **2. 35 U.S.C. §102**

The Examiner has rejected Claims 1-4, 6 and 8-19 under 35 U.S.C. § 102(e) “as being anticipated by Humphrey (‘239).” The Examiner contends:

Humphrey teaches systems, methods and devices for stimulating and regulating body organ function, particularly in relation to paralyzed muscles of an arm (Figures 1, 10, 11). The method includes collecting waveforms from the brain or nervous system that are representative of waveforms naturally occurring within a body from a body; at least temporarily storing the collected waveforms in a storage medium of a computer processor (9); and transmitting a first waveform signal including at least a second waveform that substantially corresponds to one or more collected waveforms to the body organ to stimulate organ function. The collected waveforms are transformed from analog signals into a readable digital format for the computer processor. The collected waveforms are stored according to the function performed by the waveforms. The collected waveforms are transmitted to the paralyzed muscles through a stimulation controller that converts the digital signals to analog signals. The system includes a computer (9) forming a source of collected waveforms; means for transmitting at least one of the collected waveforms to a body organ; and means for applying the transmitted waveforms to the body organ. The transmitting means includes a digital to analog converter and the applying means can include a body electrode applied to the paralyzed muscles of the arm. The computer at least temporarily stores the waveforms in a digital format in separate storage areas (102) for collected waveforms of different functional categories. Recording electrodes (5) are placed on the body to collect the waveforms in analog form and transmit the waveforms to the computer source. (emphasis added)

The Examiner has also rejected Claims 1, 6, 10-12, 15, 16, 21 and 22 under 35 U.S.C. §102(b) “as being anticipated by Kennedy (‘573)”. The Examiner contends:

Kennedy teaches a system and method for stimulating and regulating body organ function. The method includes collecting waveforms from the brain or nervous system that are representative of waveforms naturally occurring within a body from a body; at least temporarily storing the collected waveforms in a storage medium (33); and transmitting a first waveform signal including at least a second waveform that substantially corresponds to one or more collected waveforms to the nervous system to stimulate organ function. The system includes a source of collected waveforms (33); means for transmitting (22, 31) at least one of the collected waveforms to a body organ; and means for applying (30, 58) the transmitted waveforms to the body organ. Recording electrodes (30, 58) are placed on the body to collect the waveforms in analog form and transmit the waveforms to the storage medium.

It is well established that a rejection for anticipation under § 102 requires that each and every limitation of the claimed invention be disclosed in a single prior art reference. *See In re Paulsen*, 30 F.3d 1475, 1478-79, 31 U.S.P.Q. 2d 1671, 1673 (Fed. Cir. 1994); *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 18 U.S.P.Q. 2d 1001 (Fed. Cir.1991). *See also American Permahedge, Inc. v. Barcana, Inc.*, 857 F. Supp. 308, 32 U.S.P.Q. 2d 1801, 1807-08 (S.D. NY 1994) (“Prior art anticipates an invention ... if a single prior art reference contains each and every element of the patent at issue, operating in the same fashion to perform the identical function as the patent product. ... Thus, any degree of physical difference between the patented product and the prior art, *no matter how slight*, defeats the claim of anticipation.”); *Transco Ex parte Levy*, 17 U.S.P.Q. 2d 1461, 1462 (Bd. Pat. App. & Int’l 1990) (“[I]t is incumbent upon the examiner to identify wherein each and every facet of the claimed invention is disclosed in the applied reference”).

Applicants respectfully submit that the claimed invention is **not** anticipated by Humphrey or Kennedy. As discussed in detail below, neither Humphrey, nor Kennedy disclose “each and every limitation of the claimed invention.”

**a. Humphrey**

Although Humphrey discloses the collection of waveforms (“neural signals”) from the body, Humphrey does not teach or even suggest the step of storing a plurality of collected waveforms according to the functions regulated by the collected plurality of waveforms *or* a source of collected waveforms that includes storage areas that are adapted to store the collected waveforms according to the functions regulated by the collected waveforms.

**b. Kennedy**

Kennedy discloses an implantable electrode that can be employed to collect or acquire waveforms from the body. Although Kennedy discloses that the electrode can also be employed to transmit signals to the body, Kennedy similarly does not teach or even suggest the step of storing a plurality of collected waveforms according to the functions regulated by the collected plurality of waveforms *or* a source of collected waveforms that includes storage areas that are adapted to store the collected waveforms according to the functions regulated by the collected waveforms.

Applicants thus respectfully submit that neither Humphrey, nor Kennedy disclose “each and every limitation of the claimed invention.” Applicants accordingly request that the rejections under 35 U.S.C. § 102 be withdrawn.

**3. 35 U.S.C. §103**

Applicants further submit that Claims 1 and 6 define an invention that is unobvious over the cited references, alone or in combination.

It is well established that in determining what is and what is not obvious under § 103, all properties and advantages not in the prior art must be considered. See *In re Wright*, 848 F.2d 1216, 6 U.S.P.Q. 2d 1959, 1962 (Fed. Cir. 1988) (“Factors including unexpected results, new features, solution of a different problem, novel properties, are all considerations in the determination of obviousness in terms of 35 U.S.C. § 103”). Indeed, it is the invention as a whole, including distinct functions that must be considered in obviousness determinations.

It is further well established that obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination. See *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577, 221 U.S.P.Q. 929, 922 (Fed. Cir. 1984).

As indicated above, neither Humphrey, nor Kennedy suggest the step of storing a plurality of collected waveforms according to the functions regulated by the collected plurality of waveforms *or* a source of collected waveforms that includes storage areas that are adapted to store the collected waveforms according to the functions regulated by the collected waveforms.

Applicants thus respectfully submit that the inventions embodied in Claims 1 and 6, as amended, are unobvious in view of Humphrey and Kennedy, alone or in combination.

#### **4. Double Patenting**

The Examiner has also indicated that, even if Claim 6 were deemed not anticipated by and unobvious in view of the cited references, it is likely that Claim 6 would be rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-10 of U.S. Pat. No. 6,775,573 and Claims 1-14 of U.S. Pat. No. 6,937,903. The Examiner indicated that although the conflicting claims are not identical, they do not appear to be patentably distinct from each other since controlling respiration is achieved by regulating body organ function.

Applicants are accordingly submitting herewith the requisite Terminal Disclaimers to overcome the anticipated double-patenting rejection.

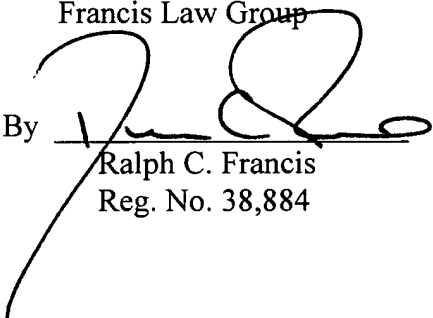
### **III. CONCLUSION**

Applicants, having answered each and every ground of objection and rejection as set forth by the Examiner, and having added no new matter, believe that this amendment clearly overcomes the references of record, and now submit that Claims 1, 6, 10, 11 and 15 in the above referenced patent application are in condition for allowance and the same is respectfully solicited.

If the Examiner has any further questions or comments, Applicants invite the Examiner to contact their Attorneys of record at the telephone number below to expedite prosecution of the application.

Respectfully submitted,  
Francis Law Group

By



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